IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT-CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, Attorney General of the State of Illinois,))
Attorney General of the State of Inmois,)
Plaintiff,) - AGA87
vs.) 10CH46487.
BAYER HEALTHCARE, LLC	FULED
Defendant.	OCT 26 2010) clerk of the circuit court of cook county, it

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

1. Plaintiff, the PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, Attorney General of the State of Illinois, brings this action complaining of Defendant BAYER HEALTHCARE, LLC, a New Jersey corporation, for violating the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq., and the Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 et seq., as follows:

JURISDICTION AND VENUE

- 2. This action is brought for and on behalf of the PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, Attorney General of the State of Illinois, pursuant to the provisions of the Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq., and the Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 et seq.
- 3. This Court has jurisdiction over the Defendant pursuant to section 2-209(a)(1) of the Illinois Code of Civil Procedure, 735 ILCS 5/2-209(a)(1), because the Defendant has transacted business within the State of Illinois at all times relevant to this complaint.

4. Venue for this action properly lies in Cook County, Illinois, pursuant to section 2-101 and 2-102(a) of the Illinois Code of Civil Procedure, 735 ILCS 5/2-101, 735 ILCS 5/2-102(a) because Defendant transacts business in Cook County, Illinois and/or some of the transactions out of which this action arose occurred in Cook County, Illinois.

PARTIES

- 5. Plaintiff, the PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, Attorney General of the State of Illinois, is charged, inter alia, with the enforcement of the Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq. and Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 et seq.
- 6. Defendant BAYER HEALTHCARE LLC (hereinafter "Bayer" or "Defendant") is a healthcare and medical products company with its U.S. headquarters for one of its division's, Bayer Consumer Care, in Morristown, New Jersey.

COMMERCE

7. Subsection 1(f) of the Consumer Fraud and Deceptive Business Practices Act, defines "trade" and "commerce" as follows:

The terms 'trade' and 'commerce' meant the advertising, offering for sale, sale, or distribution of any services and property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value wherever situated, and shall include any trade or commerce directly or indirectly affecting the people of this State.

815 ILCS 505/1(f).

8. Defendant was at all times relative hereto, engaged in trade or commerce in the State of Illinois, to wit: advertising, selling, promoting and distributing Bayer Men's One A Day Vitamins.

BACKGROUND

- 9. Bayer manufactures, markets, and promotes One-A-Day Vitamins nationally and in Illinois. The One-A-Day brand is divided into various sub-brands that target particular populations of consumers by age and sex. One-A-Day Men's Health Formula targets males and One-A-Day Men's 50+ vitamins target men 50 years of age and older. (Henceforth, these two products shall collectively be referred to as "One-A-Day Men's," "OAD Men's Products" or "OAD Men's."
- leveraging fear of prostate cancer. Bayer made both express and implied promotional claims that misrepresented that OAD Men's Products reduce a man's risk of developing prostate cancer. Bayer made these claims despite the fact that Bayer knew, or should have known, that the ingredients in OAD Men's Products do not decrease the risk of prostate cancer; in fact, Bayer knew or should have known that for some men, high doses of the ingredients found in Bayer OAD Men's Vitamins, such as zinc and selenium, may *increase* the risk of an aggressive and deadly form of prostate cancer. Accordingly, Bayer's promotion of OAD Men's Products was both deceptive and unfair.

DEFENDANT'S COURSE OF COUNDUCT

A. PROSTATE CANCER CLAIMS - LYCOPENE

11. To support its initial prostate cancer claim, Bayer relied upon the ingredient lycopene. Starting in 2005, Bayer television advertisements claimed that "one in three men" had prostate problems and that OAD Men's Health Formula with lycopene "supports prostate health." Bayer knew, or should have known, that substantial numbers of viewers understood

these claims to mean that OAD Men's Health Formula with lycopene reduced a man's risk of developing prostate cancer. Moreover, Bayer's lycopene advertisements cited "Harvard studies" to substantiate the prostate health claim. However, these studies related solely to prostate cancer and no other aspect of prostate health. Thus, any consumer who actually checked the studies would know that Bayer intended to make a lycopene cancer claim. Nonetheless, the studies that Bayer cited were not competent and reliable scientific evidence sufficient to substantiate the lycopene prostate cancer claim. In a 2005 enforcement discretion letter issued by FDA that reviewed the totality of the science concerning lycopene and prostate cancer, FDA concluded that, although "very limited and preliminary scientific research suggests" tomato products (which contain lycopene) may reduce the risk of prostate cancer, there is "no credible evidence" to substantiate such a claim for lycopene supplements [such as OAD Men's].

B. PROSTATE CANCER CLAIMS - SELENIUM

12. Starting in 2006, Bayer OAD Men's Health Formula advertisements stopped emphasizing lycopene and started using selenium to support the prostate cancer prevention claim. Bayer believed it could make such a claim because in 2003, FDA issued an enforcement discretion letter that announced FDA would not prosecute the qualified health claim "[s]elenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer." However, Bayer's express cancer claims regarding selenium did not comply with the language FDA announced it would tolerate. Rather, Bayer used language such as: "Did you know that 1 in 3 men will face prostate issues" alongside "emerging research suggests Selenium may reduce the risk of prostate cancer." A copy of one such print advertisement is attached hereto as Exhibit A. Such language is inconsistent with the 2003 qualified health claim. Moreover, it is deceptive because by 2006,

and especially after October 2008, the "emerging science" selenium prostate cancer claim was incorrect and misrepresented the scientific substantiation for the claim. Bayer used this deceptive selenium cancer claim in television and print advertising through June 2009 and used it in OAD Men's Health Formula packaging that was on store shelves as late as May 2010.

C. MAJOR LEAGUE BASEBALL: THE "STRIKE OUT PROSTATE CANCER" PROMOTION

League Baseball that allowed Bayer to promote OAD Men's products during baseball games and allowed Bayer to use major league baseball graphics and players to promote OAD Men's products. As part of this promotion, Bayer engaged in a "strike out prostate cancer" campaign that was ostensibly to raise money for prostate cancer research but in fact, was a vehicle to make deceptive claims that OAD Men's helped prevent prostate cancer. Through billboards, print and broadcast advertisements, and interviews with professional baseball spokespersons, Bayer's Major League Baseball promotional campaign made express and implied claims that OAD Men's Products reduced the risk of prostate cancer. A copy of one such print advertisement is attached hereto as Exhibit B. In fact, by October 2008, it was clear that OAD Men's Products provided no such benefit.

D. EMERGING SCIENCE SUBMERGES BAYER'S PROSTATE CANCER CLAIMS

14. Although in 2003, using the methodology then used by FDA (which has since been rejected) to evaluate and weight scientific studies, there may have been sufficient science to support the limited qualified health claim approved by FDA regarding selenium and cancer, over

time, the science supporting the qualified claim grew progressively weaker. Rather than strengthening the selenium prostate cancer claim, "emerging science," submerged the claim beneath a rising tide of negative scientific studies. This process culminated in October 2008. when the results of the clinical trial known as The Selenium and Vitamin E Cancer Prevention Trial ("SELECT") became public. SELECT was funded by the National Institute of Health and was designed to definitively determine whether vitamin E and/or selenium reduce the risk of prostate cancer. This prospective, randomized, controlled, double-blind study was the largest and best designed clinical trial relating to selenium and prostate cancer ever conducted. At the time SELECT was designed, hopes were high that it would show a benefit for selenium and vitamin E against prostate cancer; however, these hopes were dashed when the Data Safety Monitoring Board² for SELECT was forced to stop the study after preliminary results showed selenium provided no such benefit and might actually cause study subjects harm. After SELECT, there was broad scientific consensus that selenium did not prevent prostate cancer. Nevertheless, Bayer continued to promote OAD Men's Health Formula with the "emerging science" selenium prostate cancer claim.

¹ Li et al, A prospective study of plasma selenium levels and prostate cancer risk, Journal of the National Cancer Institute, 2004; 96:696-703. Peters et al, Serum selenium and risk of prostate cancer: a nested case-control study. American Journal of Clinical Nutrition, 2007; 85:209-217. Peters et al, Vitamin E and selenium supplementation and risk of prostate cancer in the Vitamins and Lifestyle (VITAL) study cohort, Cancer Causes Control, 2008; 19:75-87.

² A Data Safety Monitoring Board or "DSMB" is an independent body tasked with ensuring the safety of participants in clinical trials. The DSMB has access to unblended study data which is reviewed to ensure that there is sufficient benefit to justify the risks. If such is not the case, the DSMB is ethically required to terminate the clinical trial.

E. BAYER IMPROPERLY CONTINUED TO RELY ON THE 2003 SELENIUM CANCER CLAIM

15. Although Bayer had an independent duty to ensure that there was competent and reliable scientific evidence to substantiate all promotional claims regarding selenium and prostate cancer, Bayer chose instead to ignore the weight of scientific evidence to the contrary and relied upon the obsolete and inapplicable 2003 FDA letter to justify continued use of the claim. Bayer relied on the obsolete 2003 selenium enforcement discretion letter even though Bayer knew, as early as 2007, that FDA was in the process of reviewing the claim and even though Bayer knew, or should have known, that by January 2009, FDA had finalized and published its revised methodology for evaluating qualified health claims and that under that revised methodology, it was virtually certain that the 2003 selenium discretion letter would be replaced. Yet Bayer continued to rely on weak science³ to actively advertise and promote OAD Men's Health with a selenium prostate cancer claim. It was not until June of 2009, when FDA formally issued a revised enforcement discretion letter regarding selenium and cancer that Bayer seriously considered revising its Selenium prostate cancer claim. In the 2009 version, FDA held

³ To substantiate its selenium cancer claim, Bayer relied primarily on seven secondary post-hoc analyses of a single trial, the Nutritional Prevention of Cancer ("NPC") trial. This clinical trial evaluated the relationship between supplemental selenium and skin cancer risk, which was the primary predefined end-point of the study. The seven post hoc analyses sought to "data mine" for other types of cancer, including prostate cancer; however, such data mining is only beneficial for generating hypotheses to be tested in future studies and not to substantiate efficacy claims. (In fact, the suggestions raised by NPC generated the hypotheses that were tested by SELECT). In its 2009 review of the scientific evidence concerning the relationship between supplemental selenium and cancer, FDA determined that "scientific conclusions about selenium supplements and secondary cancers [including prostate cancer] could not be drawn from the seven [NPC] reports . . ."

that "it is highly unlikely that selenium supplements reduce the risk of prostate cancer." It was only then that Bayer announced that it would stop making its selenium cancer claim to promote OAD Men's Products; however, Bayer failed to make this change in their product labeling until much later.

F. BAYER CONTINUED TO DISSEMINATE THE DECEPTIVE SELENIUM PROSTATE CANCER CLAIM

16. Even after FDA formally revised the 2003 selenium cancer claim and after Bayer publicly announced it would stop making the prostate cancer promotional claim, Bayer made no attempt to withdraw or recall OAD Men's Products with deceptive prostate cancer messaging. Rather, Bayer continued to manufacture and distribute OAD Men's Product with the deceptive prostate claim through November 2009. Because of Bayer's failure to take timely action, OAD Men's Products with deceptive prostate packaging remained on store shelves until at least May 2010 – more than 18 months after the SELECT study definitively showed that selenium was ineffective and almost one year after Bayer publicly announced that it would stop making prostate cancer claims in its packaging and promotion of OAD Men's Health.

G. MULTIVITAMINS WITH THE INGREDIENTS FOUND IN OAD MEN'S MAY WORSEN PROSTATE CANCER

17. In addition to demonstrating that selenium had no beneficial impact, SELECT raised serious concerns that selenium might have a negative impact on men's health. These

⁴ In October, 2010, following litigation between FDA and a supplement manufacturer, FDA revised the qualified health claim to: "Selenium may reduce the risk of prostate cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer."

concerns were so great that the SELECT DSMB took the extraordinary step of stopping the study midstream. Moreover, starting in 2007, there was mounting scientific evidence that raised significant concerns that multivitamins containing the ingredients found in OAD Men's Products might increase the risk of particularly aggressive prostate cancers in certain people. Despite the mounting evidence that for some men, the ingredients in OAD Men's vitamins may have a negative impact on prostate health, Bayer unconscionably persisted in promoting OAD Men's Vitamins as supporting prostate health and reducing the risk of prostate cancer, without disclosing that OAD Men's vitamins might very well have the opposite effect.

APPLICABLE STATUTES

18. Section 2 of the Consumer Fraud and Deceptive Business Practices Act, states in relevant part as follows:

Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in section 2 of the 'Uniform Deceptive Trade Practices Act', approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

815 ILCS 505/2.

⁵ Lawson et al, Multivitamin Use and Risk of Prostate Cancer in the National Institutes of Health – AARP Diet and Health Study, Journal of the National Cancer Institute, 2007; 99:754-64. Zhang et al, Vitamin and mineral use and risk of prostate cancer: the case-control surveillance study, Cancer Causes Control, 2009; 20:691-698. Chan et al, Plasma Selenium, Manganese Superoxide Dismutase, and Intermediate- or High-Risk Prostate Cancer, Journal of Clinical Oncology, 2009; 27:3577-3583.

- 19. Section 2 of the Uniform Deceptive Trade Practices Act, states in relevant part as follows:
 - (a) A person engages in a deceptive trade practice when, in the course of his or her business, vocation or occupation, the person:
 - (5) represents that goods or services have sponsorship, ingredients, uses, benefits, or quantities that they do not have...;
 - (12) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.
 - (b) In order to prevail in an action under this Act, a plaintiff need not prove competition between the parties or actual confusion or misunderstanding.

815 ILCS 510/2.

- 20. Section 1 of the Uniform Deceptive Trade Practices Act, states in relevant part as follows:
 - (5) "person" means an individual, corporation...or any other legal or commercial entity.

815 ILCS 510/1.

VIOLATIONS OF LAW

COUNT I - CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

- 21. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 20.
- 22. Defendants in the course of advertising, offering for sale, selling and promotion of its OAD Men's Products have engaged in a course of trade of commerce which constitutes unfair and deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud and Deceptive Business Practices Act by misrepresenting that One-A-Day Men's Health Formula

and One-A-Day Men's 50+ vitamins reduce a man's risk of developing prostate cancer and "support prostate health."

COUNT II – UNIFORM DECEPTIVE TRADE PRACTICES ACT

- 23. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 20.
- 24. Defendants in the course of advertising, offering for sale, selling and promotion of its OAD Men's Products have engaged in a course of trade of commerce which constitutes unfair and deceptive acts or practices declared unlawful under Section 2 of the Consumer Fraud and Deceptive Business Practices Act by misrepresenting that One-A-Day Men's Health Formula and One-A-Day Men's 50+ vitamins reduce a man's risk of developing prostate cancer and "support prostate health."
- 25. Defendants in the course of advertising, offering for sale, selling and promotion of its OAD Men's Products have engaged in a course of trade of commerce which constitutes unfair and deceptive acts or practices declared unlawful under Section 2 of the Uniform Deceptive Trade Practices Act by promoting, One-A-Day Men's Health Formula and One-A-Day Men's 50+ vitamins to protect against prostate cancer without disclosing that some of the ingredients in these products that were promoted to support prostate health may *increase* the risk of an aggressive and deadly form of prostate cancer.

<u>REMEDIES</u>

- 1. Section 7 of the Consumer Fraud Act states in relevant part as follows:
 - (a) Whenever the Attorney General has reason to believe that any person is using, has used, or is about to use any method, act or practice declared by the Act to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the State against such person to restrain by preliminary or permanent injunction the use of such method, act or practice. The

Court, in its discretion, may exercise all powers necessary, including but not limited to: injunction, revocation, forfeiture or suspension of any license, charter, franchise, certificate or other evidence of authority of any person to do business in this State; appointment of a receiver; dissolution of domestic corporations or associations; suspension or termination of the right of foreign corporations or associations to do business in this State; and restitution.

- (b) In addition to the remedies provided herein, the Attorney General may request and this Court may impose a civil penalty in a sum not to exceed \$50,000 against any person found by the Court to have engaged in any method, act or practice declared unlawful under this Act. In the event the court finds the method, act or practice to have been entered into with intent to defraud, the court has the authority to impose a civil penalty in a sum not to exceed \$50,000 per violation.
- (c) In addition to any other civil penalty provided in this Section, if a person is found by the court to have engaged in any method, act, or practice declared unlawful under this Act, and the violation was committed against a person 65 years of age or older, the court may impose an additional civil penalty not to exceed \$10,000 per violation.

815 ILCS 505/7 (2006).

2. Section 10 of the Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/10, provides:

In any action brought under the provisions of this Act, the Attorney General is entitled to recover costs for the use of this State.

3. Section 3 of the Uniform Deceptive Trade Practices Act, 815 ILCS 510/3, provides:

A person likely to be damaged by a deceptive trade practice of another may be granted injunctive relief upon terms that the court considers reasonable. Proof of monetary damage, loss of profits or intent to deceive is not required.

The relief provided in this Section is in addition to remedies otherwise available against the same conduct under the common law or other statutes of this State.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief as follows:

- A. For judgment against Defendant for civil penalties of up to \$50,000 for each willful violation of the Consumer Fraud and Deceptive Practices Act, as provided by Section 7 of the Consumer Fraud Act, 815 ILCS 505/7;
- B. Ordering the Defendant to pay all costs for the prosecution and investigation of this action, as provided by Section 10 of the Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/10;
- C. Issuing a permanent injunction prohibiting the Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive conduct, as provided by Section 7 of the Consumer Fraud Act, 815 ILCS 505/7 and Section 3 of the Uniform Deceptive Trade Practices Act, 815 ILCS 510/3;
- D. For judgment awarding the following injunctive relief pursuant to Section 3 of the Uniform Deceptive Trade Practices Act, 815 ILCS 510/3;
 - Bayer, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of One A Day Men's Health Formula and One A Day Men's 50+ Advantage, in or affecting commerce, shall not make, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including but not limited to the representation that One A Day Men's

Health Formula and One A Day Men's 50+ Advantage reduces the risk of prostate cancer.

- In connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time the representation is made,

 Bayer possesses and relies upon Competent and Reliable Scientific Evidence.
- "Competent and Reliable Scientific Evidence" shall mean tests, analyses, research, or studies, that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results, and that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.
- 4) "Covered Product" shall mean any dietary supplement in Bayer's line of One A Day Multivitamins, including but not limited to One A Day Men's Health Formula and One A Day Men's 50+ Advantage.
- E. For a judgment granting such other and further relief as the Court deems equitable and proper.

Dated October 26, 2010.

Respectfully submitted,

THE PEOPLE OF THE
STATE OF ILLINOIS, by
LISA MADIGAN,
ILLINOIS ATTORNEY GENERAL

James D. Kole 122

Chief, Consumer Fraud Bureau

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Selenium which emerging research suggests may reduce the risk of prostate cancer Specially formulated with

ONE A DAYs Men's Health Formula 18 a complete multivitamin plus key nutrients to support a healthy Selenium may reduce the risk of prostate cancer." heart, and Selenium to support a healthy prostate." Prostate cancer is the most frequently diagnosed cancer in men, and emerging research suggests

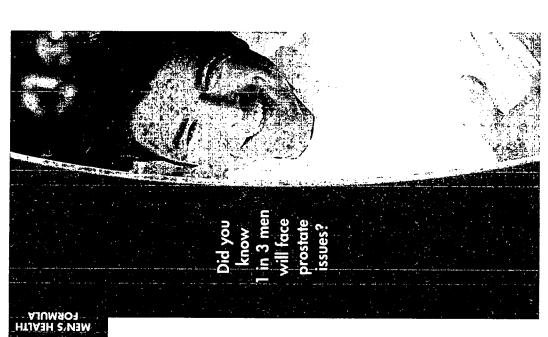
A Complete Multivitamin Plus More! for Men to Support *

- · Prostate Health with Lycopene, more' Selenium, Vitamin E and Zinc
- · Heart Health with Vitamins B6. B12, C, E and Folic Acid
- · Healthy Blood Pressure" with Calcium. Magnesium and Vitamin C

Does not contain Iron - Research suggests excess iron may increase a man's risk of heart disease

LIVESTRONG

- Compared to ONE A DAV* Essential, and with nearly write the Selenum in Centum* for provise the safe in the formal name and pressure levels already within the momal range of the properties of



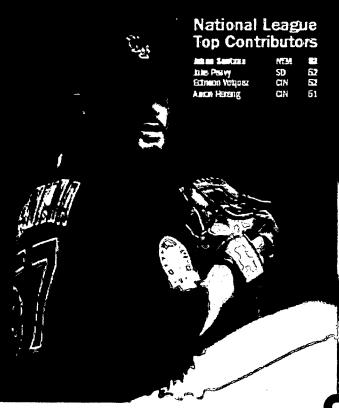


STRIKING OUT PROSTATE CANCER

ONEADAY

Men's Health





EXHIBIT

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